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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,853	08/26/2002	Frank Cuttitta	2026-4316US1	2579

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EXAMINER	
COOK, LISA V	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 05/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/070,853	CUTTITTA ET AL.	
	Examiner	Art Unit	
	Lisa V. Cook	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/19/05*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-52* is/are pending in the application.

4a) Of the above claim(s) *6-52* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-52* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/8/02, 6/3/03, 2/10/04 LVCook*
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Reconsideration

1. Applicants contend that the claimed inventions are linked by a shared special technical feature because they are all drawn to the binding complex formed between adrenomedullin (AM) and human complement factor H. Applicants further argue that the reference to Martinez et al. (Endocrinology 138:5597-5604, 1997) teaches the binding of adrenomedullin (AM) and a specific seven-transmembrane G protein associated receptor not human complement factor H. This argument has been carefully considered and was found persuasive. Examiner does not contend that the reference to Martinez et al. discloses the special technical feature involving the binding between adrenomedullin (AM) and human complement factor H. Rather, the instantly claimed inventions share only a single special technical feature and that is the measurement of adrenomedullin. Martinez clearly teaches such a measurement. Therefore, the technical feature argued by Applicant does not appear to be a contribution over the prior art.

Election/Restriction

2. Applicant's election with traverse of Group I (claims 1-5) in the reply filed on 19 December 2005 is acknowledged. The traversal is on the ground(s) that the inventions are linked by a shared special technical feature and there would be no undue burden on the Examiner to examine the claims in a single application. This is not found persuasive because although the inventions share a special technical feature, they are directed to various categories of inventions.

The instantly claimed categories include seven methods (Groups A-B, D-E, & G-I) and two products (Group C and F). However, PCT rule 37 CFR 1.475(b) indicates that claims to different categories of invention will be considered to have unity of invention if the claims are drawn *only to one of* the listed combinations of categories.

The instant claims involve multiple categories which are not listed as acceptable combinations of categories under PCT rule 37 CFR 1.475(b) and (c). Accordingly, applicant is required to elect one combination of categories for consideration.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 6-52 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected elected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 12/19/05. Currently claims 1-5 are under consideration.

Information Disclosure Statement

4. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the examiner on form PTO-892 or applicant on PTO-1449 has cited the references they have not been considered.

5. The information disclosure statements filed 3/8/02, 6/3/03, and 2/10/04 have been considered prior to first action on the merits.

Oath/Declaration

6. A new oath or declaration is required because Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c). See residence and address for inventor Ted H. Elsasser. The wording of an oath or declaration cannot be amended. If the wording is not correct or if all of the required affirmations have not been made or if it has not been properly subscribed to, a new oath or declaration is required. The new oath or declaration must properly identify the application of which it is to form a part, preferably by application number and filing date in the body of the oath or declaration. See MPEP §§ 602.01 and 602.02.

Specification

7. The disclosure is objected to because of the following informalities: Page 1 is not numbered. Appropriate correction is required.

8. The use of the trademarks has been noted in this application. (.i.e. TRITON and TWEEN on page 40, for example). They should be capitalized wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

9. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

I. Claims 1, 4, and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Kato et al. (Endocrinology, 1997, Vol.138, No.6, pages 2615-2620) in light of Wikipedia, "chaotropic agent", http://en.wikipedia.org/wiki/Chaotropic_agent, dated March 27, 2006.

Kato et al. disclose procedures to measure adrenomedullin in rat endothelial cells. See page 2615 2nd column –Cell Culture. The cell culture media (sample) was acidified with 0.1% TFA (chaotropic agent) and centrifuged to obtain a separate supernatant and solid portions of the sample. The supernatant was placed on a Sep Pak C18 cartridge and the eluates (sample fractions) were subjected to RIA. In the RIA antibodies recognizing the C-terminal region (22-50) of rat adrenomedullin were employed. See page 2616 – 1st column RIA of adrenomedullin, figure 2, and figure 3.

It is noted that Applicant has not defined chaotropic agent and Wikipedia teaches that a chaotropic agent is an agent, which causes molecular structures to be disrupted. (See attached Wikipedia).

Although the reference to Kato et al. is silent with respect to adrenomedullin being dissociated from factor H, it appears that this is an inherent property of the chaotropic agent. Since Kato et al. disclose one such chaotropic agent, 0.1% TFA (Trifluoroacetic acid) it reads on the cited claims and would dissociate adrenomedullin complexes.

II. Claims 1, 2, 4, and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Sato et al. (Life Sciences, Vol.57, No.2, pages 189-194, 1995) in light of Wikipedia, "chaotropic agent", http://en.wikipedia.org/wiki/Chaotropic_agent, dated March 27, 2006.

Sato et al. disclose procedures to measure adrenomedullin in human plasma and urine. See abstract and page 190 3rd and 4th paragraphs. The plasma and urine samples were acidified with 0.1% TFA (chaotropic agent) and centrifuged to obtain a separate supernatant and solid portions of the sample. The supernatant was placed on a Sep Pak C18 cartridge and the eluates (sample fractions) were subjected to RIA. See pages 191. In the RIA a double antibody method was utilized to measure adrenomedullin. See page 190 RIA.

It is noted that Applicant has not defined chaotropic agent and Wikipedia teaches that a chaotropic agent is an agent, which causes molecular structures to be disrupted. (See attached Wikipedia).

Although the reference to Kato et al. is silent with respect to adrenomedullin being dissociated from factor H, it appears that this is an inherent property of the chaotropic agent. Since Kato et al. disclose one such chaotropic agent, 0.1% TFA (Trifluoroacetic acid) it reads on the cited claims and would dissociate adrenomedullin complexes.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

III. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kato et al. in light of Wikipedia and Sato et al. in light of Wikipedia and further in view of Tsang et al. (Journal of Immunological Methods, Vol.138, 1991, pages 291-299).

Please see Kato et al. in light of Wikipedia and Sato et al. in light of Wikipedia as set forth above.

Kato et al. in light of Wikipedia and Sato et al. in light of Wikipedia differ from the instant invention in not specifically teaching the use of sodium thiocyanante (NaSCN).

However, Tsang et al. teach procedures for optimizing the dissociation of complexed reagents (covalently linked ligands). See abstract and page 291 – Introduction. Thirteen eluting agents were evaluated for product yield and specific activity. The reagents were chosen because of their ability to dissociate immune complexes. See page 292 column 1 – last paragraph.

Three chaotropic agents were used in the experiments. They included NaSCN, GuCl, and GuSCN. When the three-chaotropic agents were used first as dissociating regents prior to sample elution, no remaining bound material was detected on the columns. Of the three-chaotropic agents, NaSCN yielded the highest recovered total protein. See page 295 1st column -1st and 2nd paragraphs.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ sodium thiocyanate to dissociate immune complexes as taught by Tsang et al. in the methods of Kato et al. and Sato et al. in light of Wikipedia to dissociate adrenomedullin because Tsang et al. taught that when the chaotropic agents were used first as dissociating regents prior to sample elution, no remaining bound material was detected on the columns. Further, NaSCN yielded the highest recovered total protein. See page 295 1st column -1st and 2nd paragraphs. One having ordinary skill in the art would have been motivated to use the chaotropic agent NaSCN in order to achieve maximal sample recovery.

8. For reasons aforementioned, no claims are allowed.

Remarks

9. Prior art made of record and not relied upon is considered pertinent to the applicant's disclosure:

A. Anumula (US Patent #5,641,685) teach the utility of sodium thiocyanate in protein elution and sequences procedures.

10. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 – Central Fax number is (571) 273-8300, which is able to receive transmissions 24 hours/day, 7 days/week. In the event Applicant would like to fax an unofficial communication, the Examiner should be contacted for the appropriate Right Fax number.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday - Friday from 7:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (571) 272-0823.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see httpr//pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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